

AMENDED IN ASSEMBLY SEPTEMBER 4, 2001

AMENDED IN ASSEMBLY AUGUST 20, 2001

AMENDED IN ASSEMBLY JULY 3, 2001

AMENDED IN SENATE MAY 30, 2001

AMENDED IN SENATE MAY 15, 2001

SENATE BILL**No. 1169**

Introduced by Senator Alpert

(Coauthors: Assembly Members Cohn, Koretz, Richman, *Shelley*,
and Thomson)

February 23, 2001

An act to amend Section 4052 of the Business and Professions Code,
relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 1169, as amended, Alpert. Pharmacy.

Under existing law, a pharmacist may not, in general, furnish a dangerous drug except upon the prescription of a physician, dentist, podiatrist, optometrist, or veterinarian. However, existing law provides for certain exemptions.

This bill would authorize a pharmacist to initiate emergency contraception drug therapy in accordance with standardized protocols developed by the pharmacist and an authorized prescriber acting within his or her scope of practice. The bill would require a pharmacist who initiates emergency contraception drug therapy pursuant to these provisions to provide the recipient with a standardized fact sheet developed by the California State Board of Pharmacy, in consultation

with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The bill would also require that prior to performing this procedure a pharmacist complete a specified training program.

This bill would incorporate additional changes in Section 4052 of the Business and Professions Code proposed by AB 826, to be operative only if AB 826 and this bill are both enacted and become effective on or before January 1, 2002, and this bill is enacted last.

Because a violation of the Pharmacy Law is a misdemeanor, this bill would impose a state-mandated local program by creating new crimes.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4052 of the Business and Professions
- 2 Code is amended to read:
- 3 4052. (a) Notwithstanding any other provision of law, a
- 4 pharmacist may:
- 5 (1) Furnish a reasonable quantity of compounded medication
- 6 to a prescriber for office use by the prescriber.
- 7 (2) Transmit a valid prescription to another pharmacist.
- 8 (3) Administer, orally or topically, drugs and biologicals
- 9 pursuant to a prescriber's order.
- 10 (4) Perform the following procedures or functions in a licensed
- 11 health care facility in accordance with policies, procedures, or
- 12 protocols developed by health professionals, including physicians,
- 13 pharmacists, and registered nurses, with the concurrence of the
- 14 facility administrator:
- 15 (A) Ordering or performing routine drug therapy-related
- 16 patient assessment procedures including temperature, pulse, and
- 17 respiration.
- 18 (B) Ordering drug therapy-related laboratory tests.



1 (C) Administering drugs and biologicals by injection pursuant
2 to a prescriber's order (the administration of immunizations under
3 the supervision of a prescriber may also be performed outside of
4 a licensed health care facility).

5 (D) Initiating or adjusting the drug regimen of a patient
6 pursuant to an order or authorization made by the patient's
7 prescriber and in accordance with the policies, procedures, or
8 protocols of the licensed health care facility.

9 (5) (A) Perform the following procedures or functions as part
10 of the care provided by a health care facility, a licensed home
11 health agency, a licensed clinic in which there is a physician
12 oversight, a provider who contracts with a licensed health care
13 service plan with regard to the care or services provided to the
14 enrollees of that health care service plan, or a physician, in
15 accordance, as applicable, with policies, procedures, or protocols
16 of that facility, the home health agency, the licensed clinic, the
17 health care service plan, or that physician, in accordance with
18 subparagraph (C):

19 (i) Ordering or performing routine drug therapy-related patient
20 assessment procedures including temperature, pulse, and
21 respiration.

22 (ii) Ordering drug therapy-related laboratory tests.

23 (iii) Administering drugs and biologicals by injection pursuant
24 to a prescriber's order (the administration of immunizations under
25 the supervision of a prescriber may also be performed outside of
26 a licensed health care facility).

27 (iv) Adjusting the drug regimen of a patient pursuant to a
28 specific written order or authorization made by the patient's
29 prescriber for the individual patient, and in accordance with the
30 policies, procedures, or protocols of the health care facility, home
31 health agency, licensed clinic, health care service plan, or
32 physician. Adjusting the drug regimen does not include
33 substituting or selecting a different drug, except as authorized by
34 Section 4073.

35 (B) A patient's prescriber may prohibit, by written instruction,
36 any adjustment or change in the patient's drug regimen by the
37 pharmacist.

38 (C) The policies, procedures, or protocols referred to in this
39 paragraph shall be developed by health care professionals,

1 including physicians, pharmacists, and registered nurses, and, at
2 a minimum, meet all of the following requirements:

3 (i) Require that the pharmacist function as part of a
4 multidisciplinary group that includes physicians and direct care
5 registered nurses. The multidisciplinary group shall determine the
6 appropriate participation of the pharmacist and the direct care
7 registered nurse.

8 (ii) Require that the medical records of the patient be available
9 to both the patient's prescriber and the pharmacist.

10 (iii) Require that the procedures to be performed by the
11 pharmacist relate to a condition for which the patient has first been
12 seen by a physician.

13 (iv) Except for procedures or functions provided by a health
14 care facility, a licensed clinic in which there is physician oversight,
15 or a provider who contracts with a licensed health care plan with
16 regard to the care or services provided to the enrollees of that
17 health care service plan, require the procedures to be performed in
18 accordance with a written, patient-specific protocol approved by
19 the treating or supervising physician. Any change, adjustment, or
20 modification of an approved preexisting treatment or drug therapy
21 shall be provided in writing to the treating or supervising physician
22 within 24 hours.

23 (6) Manufacture, measure, fit to the patient, or sell and repair
24 dangerous devices or furnish instructions to the patient or the
25 patient's representative concerning the use of those devices.

26 (7) Provide consultation to patients and professional
27 information, including clinical or pharmacological information,
28 advice, or consultation to other health care professionals.

29 (8) Initiate emergency contraception drug therapy in
30 accordance with standardized procedures or protocols developed
31 by the pharmacist and an authorized prescriber who is acting
32 within his or her scope of practice. Prior to performing any
33 procedure authorized under this paragraph, a pharmacist shall
34 have completed a training program on emergency contraception,
35 ~~which includes delivered by an American Council on~~
36 *Pharmaceutical Education provider or another training program*
37 *approved by the board. The training program shall include, but is*
38 *not limited to, conduct of sensitive communications, quality*
39 *assurance, referral to additional services, and documentation.*

(b) (1) Prior to performing any procedure authorized by paragraph (4) of subdivision (a), a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(2) Prior to performing any procedure authorized by paragraph (5) of subdivision (a), a pharmacist shall have either (1) successfully completed clinical residency training or (2) demonstrated clinical experience in direct patient care delivery.

(3) For each emergency contraception drug therapy initiated pursuant to paragraph (8) of subdivision (a), the pharmacist shall provide the recipient of the emergency contraception drugs with a standardized fact sheet that includes, but is not limited to, the indications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Health Services, the American College of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. The provisions of this section do not preclude the use of existing publications developed by nationally recognized medical organizations.

(c) Nothing in this section shall affect the requirements of existing law relating to maintaining the confidentiality of medical records.

(d) Nothing in this section shall affect the requirements of existing law relating to the licensing of a health care facility.

SEC. 2. Section 4052 of the Business and Professions Code is amended to read:

4052. (a) Notwithstanding any other provision of law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded medication to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer, orally or topically, drugs and biologicals pursuant to a prescriber's order.

(4) Perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:

1 (A) Ordering or performing routine drug therapy-related
2 patient assessment procedures including temperature, pulse, and
3 respiration.

4 (B) Ordering drug therapy-related laboratory tests.

5 (C) Administering drugs and biologicals by injection pursuant
6 to a prescriber's order (the administration of immunizations under
7 the supervision of a prescriber may also be performed outside of
8 a licensed health care facility).

9 (D) Initiating or adjusting the drug regimen of a patient
10 pursuant to an order or authorization made by the patient's
11 prescriber and in accordance with the policies, procedures, or
12 protocols of the licensed health care facility.

13 (5) (A) Perform the following procedures or functions as part
14 of the care provided by a health care facility, a licensed home
15 health agency, a licensed clinic in which there is a physician
16 oversight, a provider who contracts with a licensed health care
17 service plan with regard to the care or services provided to the
18 enrollees of that health care service plan, or a physician, in
19 accordance, as applicable, with policies, procedures, or protocols
20 of that facility, the home health agency, the licensed clinic, the
21 health care service plan, or that physician, in accordance with
22 subparagraph (C):

23 (i) Ordering or performing routine drug therapy-related patient
24 assessment procedures including temperature, pulse, and
25 respiration.

26 (ii) Ordering drug therapy-related laboratory tests.

27 (iii) Administering drugs and biologicals by injection pursuant
28 to a prescriber's order (the administration of immunizations under
29 the supervision of a prescriber may also be performed outside of
30 a licensed health care facility).

31 (iv) Initiating or adjusting the drug regimen of a patient
32 pursuant to a specific written order or authorization made by the
33 patient's prescriber for the individual patient, and in accordance
34 with the policies, procedures, or protocols of the health care
35 facility, home health agency, licensed clinic, health care service
36 plan, or physician. Adjusting the drug regimen does not include
37 substituting or selecting a different drug, except as authorized by
38 the protocol. The pharmacist shall provide written notification to
39 the patient's prescriber, or enter the appropriate information in an

1 electronic patient record system shared by the prescriber, of any
2 drug regimen initiated pursuant to this clause within 24 hours.

3 (B) A patient's prescriber may prohibit, by written instruction,
4 any adjustment or change in the patient's drug regimen by the
5 pharmacist.

6 (C) The policies, procedures, or protocols referred to in this
7 paragraph shall be developed by health care professionals,
8 including physicians, pharmacists, and registered nurses, and, at
9 a minimum, meet all of the following requirements:

10 (i) Require that the pharmacist function as part of a
11 multidisciplinary group that includes physicians and direct care
12 registered nurses. The multidisciplinary group shall determine the
13 appropriate participation of the pharmacist and the direct care
14 registered nurse.

15 (ii) Require that the medical records of the patient be available
16 to both the patient's prescriber and the pharmacist.

17 (iii) Require that the procedures to be performed by the
18 pharmacist relate to a condition for which the patient has first been
19 seen by a physician.

20 (iv) Except for procedures or functions provided by a health
21 care facility, a licensed clinic in which there is physician oversight,
22 or a provider who contracts with a licensed health care plan with
23 regard to the care or services provided to the enrollees of that
24 health care service plan, require the procedures to be performed in
25 accordance with a written, patient-specific protocol approved by
26 the treating or supervising physician. Any change, adjustment, or
27 modification of an approved preexisting treatment or drug therapy
28 shall be provided in writing to the treating or supervising physician
29 within 24 hours.

30 (6) Manufacture, measure, fit to the patient, or sell and repair
31 dangerous devices or furnish instructions to the patient or the
32 patient's representative concerning the use of those devices.

33 (7) Provide consultation to patients and professional
34 information, including clinical or pharmacological information,
35 advice, or consultation to other health care professionals.

36 (8) Initiate emergency contraception drug therapy in
37 accordance with standardized procedures or protocols developed
38 by the pharmacist and an authorized prescriber who is acting
39 within his or her scope of practice. Prior to performing any
40 procedure authorized under this paragraph, a pharmacist shall

1 have completed a training program on emergency contraception,
2 which includes, but is not limited to, conduct of sensitive
3 communications, quality assurance, referral to additional services,
4 and documentation.

5 (b) (1) Prior to performing any procedure authorized by
6 paragraph (4) of subdivision (a), a pharmacist shall have received
7 appropriate training as prescribed in the policies and procedures
8 of the licensed health care facility.

9 (2) Prior to performing any procedure authorized by paragraph
10 (5) of subdivision (a), a pharmacist shall have either (1)
11 successfully completed clinical residency training or (2)
12 demonstrated clinical experience in direct patient care delivery.

13 (3) For each emergency contraception drug therapy initiated
14 pursuant to paragraph (8) of subdivision (a), the pharmacist shall
15 provide the recipient of the emergency contraception drugs with
16 a standardized fact sheet that includes, but is not limited to, the
17 indications for use of the drug, the appropriate method for using
18 the drug, the need for medical followup, and other appropriate
19 information. The board shall develop this form in consultation
20 with the State Department of Health Services, the American
21 College of Obstetricians and Gynecologists, the California
22 Pharmacists Association, and other health care organizations. The
23 provisions of this section do not preclude the use of existing
24 publications developed by nationally recognized medical
25 organizations.

26 (c) Nothing in this section shall affect the requirements of
27 existing law relating to maintaining the confidentiality of medical
28 records.

29 (d) Nothing in this section shall affect the requirements of
30 existing law relating to the licensing of a health care facility.

31 SEC. 3. Section 2 of this bill incorporates amendments to
32 Section 4052 of the Business and Professions Code proposed by
33 both this bill and AB 826. It shall only become operative if (1) both
34 bills are enacted and become effective on or before January 1,
35 2002, (2) each bill amends Section 4052 of the Business and
36 Professions Code, and (3) this bill is enacted after AB 826, in
37 which case Section 1 of this bill shall not become operative.

38 SEC. 4. No reimbursement is required by this act pursuant to
39 Section 6 of Article XIII B of the California Constitution because
40 the only costs that may be incurred by a local agency or school

1 district will be incurred because this act creates a new crime or
2 infraction, eliminates a crime or infraction, or changes the penalty
3 for a crime or infraction, within the meaning of Section 17556 of
4 the Government Code, or changes the definition of a crime within
5 the meaning of Section 6 of Article XIII B of the California
6 Constitution.

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